

**Notice of Allowability**

Application No.

10/700,158

Examiner

David Montanari

Applicant(s)

TSAI ET AL.

Art Unit

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/09/2006.
2. ☒ The allowed claim(s) is/are 10-11, and 18-29.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kent Cheng on 1/21/2006.

The application has been amended as follows:

#### **IN THE CLAIMS:**

Claim 10: A method of producing a transgenic mouse comprising: introducing a vector into a mouse embryo or a mouse ES cell and transferring said ES cell into a blastocyst; transferring said embryo or said blastocyst comprising said ES cell into a pseudopregnant female mouse; allowing said embryo or blastocyst to develop into an offspring; selecting an offspring that expresses agouti cDNA and has a coat color phenotype; wherein said vector comprises: a first transgene expression cassette comprising mouse agouti cDNA operably linked to a human keratinocyte specific K14 promoter, a second transgene expression cassette comprising RNA polymerase II large subunit promoter, and a chicken beta-globin HS4 insulator; wherein said insulator and said first transgene expression cassette are located at the 5' or 3' end of said second transgene expression cassette; the number of copies of said chicken beta-globin HS4 insulator is 1-6; and said insulator is in the same or opposite orientation relative to said first and second transgene expression cassettes in said vector.

Claim 11: A vector comprising a first transgene expression cassette comprising mouse agouti cDNA operably linked to a human keratinocyte specific K14 promoter, a second transgene expression cassette comprising RNA polymerase II large subunit promoter, and a chicken beta-globin HS4 insulator; wherein said insulator and said first transgene expression cassette are located at the 5' or 3' end of said second transgene expression cassette; the number of copies of said chicken beta-globin HS4 insulator is 1-6 and said insulator is in the same or opposite orientation relative to said first and second transgene expression cassettes in said vector.

Claim 18: A method of producing a transgenic mouse comprising: introducing a vector into a mouse embryo or a mouse ES cell and transferring said ES cell into a blastocyst; transferring said embryo or said blastocyst comprising said ES cell into a pseudopregnant female mouse; allowing said embryo or blastocyst to develop into an offspring; selecting an offspring that expresses agouti cDNA and has a coat color phenotype; wherein said vector comprises: a first transgene expression cassette comprising mouse agouti cDNA operably linked to a promoter, a second transgene expression cassette comprising RNA polymerase II large subunit promoter, and a chicken beta-globin HS4 insulator.

Claim 19: The method of claim 18 wherein said promoter is a human keratinocyte specific K14 promoter.

Claim 20: The method of claim 18 where said promoter is a mouse tyrosinase promoter.

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Claim 21: The method of claim 18 wherein said insulator and said first transgene expression cassette are placed at the 5' and 3' end of said second transgene expression cassette.

Claim 22. The method of claim 18 wherein said number of copies of said chicken beta-globin HS4 insulator is 1-6.

Claim 23. The method of claim 18 wherein said insulator is in the same or opposite orientation relative to said first and second transgene expression cassettes.

Claim 24. A vector comprising a first transgene expression cassette comprising mouse agouti cDNA operably linked to a promoter, a second transgene expression cassette comprising RNA polymerase II large subunit promoter, and a chicken beta-globin HS4 insulator.

Claim 25. The vector of claim 24 wherein said promoter is a human keratinocyte specific K14 promoter.

Claim 26. The vector of claim 24 wherein said promoter is a mouse tyrosinase promoter.

Claim 27. The vector of claim 24 wherein said insulator and said first transgene expression cassette are placed at the 5' or 3' end of said second transgene expression cassette.

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Claim 28. The vector of claim 24 wherein the number of copies of said chicken beta-globin HS4 insulator is 1-6.

Claim 29. The vector of claim 24 wherein said insulator is in the same or opposite orientation relative to said first and second transgene expression cassettes.

The following is an examiner's statement of reasons for allowance: The art of record does not teach or suggest the instantly claimed method of producing a transgenic mouse, and vector used in said method.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ram R. Shukla', with a long horizontal flourish extending to the right.

**RAM R. SHUKLA, PH.D.  
SUPERVISORY PATENT EXAMINER**

David A. Montanari, PhD